California Environmental Contaminant Biomonitoring Program: A Proposed Approach to Collecting, Analyzing and Reporting Data on Environmental Contaminants in Californians

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This document describes a proposal for establishing the California Environmental Contaminant Biomonitoring Program (CECBP). The proposed program represents a collaboration of three state departments: The Office of Environmental Health Hazard Assessment (OEHHA) and the Department of Toxic Substances Control (DTSC) in California Environmental Protection Agency (Cal/EPA), and the Department of Health Services (DHS) in the Health and Human Services Agency, with the Department of Health Services serving as the lead entity. In that capacity, DHS will work with to maximize efficiencies and eliminate duplication of effort between and among the participating entities. DHS will also serve as the primary point of coordination for the project. The purpose of the CECBP would be to systematically collect, analyze and archive blood and other human biological specimens from a statistically valid, representative sample of California's population.

The CECBP's findings would be used to:

1) Determine baseline levels of environmental contaminants in Californians, that is, a range of values representative of California's general population that can be used by physicians and scientists to compare with contaminant levels measured in specific individuals or subpopulations;
2) Establish time trends, which are trends in levels of these contaminants in people over time;
3) Assess the effectiveness of public health efforts and regulatory programs to reduce exposures of Californians to specific chemicals.

California spends $1 billion annually on environmental programs. This biomonitoring program would give state scientists and regulators the ability to evaluate some existing programs, identify and prioritize emerging environmental health issues, and provide a solid basis for future policy and budgetary decisions. Researchers could also use this information in follow-up studies to determine whether specific individuals or groups have had unusually high exposures to these contaminants, due to their occupations, lifestyles, place of residence or other factors. Ultimately, this information could give researchers new insights into links between environmental contaminants and chronic diseases.

By directly measuring levels of potentially toxic contaminants in the body, biomonitoring can produce important information that traditional air, water and soil monitoring cannot provide. Biomonitoring data can help scientists and policymakers answer such important questions as: To what extent have Californians been exposed to high levels of mercury as a result of eating fish? To what extent are Californians being exposed to phthalates in consumer products? Will the pending ban on two types of PBDE chemical

flame retardants adequately reduce human exposure to these bioaccumulative substances?

Biomonitoring can provide an accurate assessment of how many people in California have significant levels of these chemicals or their metabolites in their bodies. The value of biomonitoring comes with being able to compare chemical levels seen in different groups (for example, those of different ethnicities), and use information on differences in the groups' activities or lifestyles to identify possible sources of exposure. Information on levels of particular chemicals seen in humans, when combined with information on the toxicity of the chemicals and their metabolites, can also be used to provide some sense of potential health risks faced by the general population. However, the most important use of biomonitoring information is to identify sources of exposure to toxic chemicals, particularly those that remain in the body for long periods of time. This information would help regulators determine the need for, and magnitude of, regulations concerning the chemicals in question.

The following pages outline: (i) the proposed CECBP, including the background for the proposal and a summary of its components, and (ii) a timeline for program development and implementation.

The proposed CECBP: Background and program components

BACKGROUND

Scientific studies have identified a multitude of environmental chemicals as toxic to humans, but with few exceptions, relatively little is known about the presence of these chemicals inside the body or the magnitude of the associated health risks.

Over the past several years there have been legislative attempts to implement parts of a biomonitoring program. However, none of these legislative proposals would have established a valid statewide California baseline, meshed adequately with the 2003 DHS Biomonitoring Plan, DTSC's 20 year ongoing biomonitoring studies on dioxins, furans, PCBs and PBDEs and the existing national biomonitoring program at the U.S. Centers for Disease Control and Prevention (CDC), or created a reliable database that could be used as a foundation for future health based scientific research. While recognizing the significant flaws in the previous legislation, the Governor acknowledged the potential benefits of biomonitoring, while expressing reservations about the specific program proposed by the bill. The veto message read in part, "Because a properly constructed biomonitoring program could yield useful data for researchers, I am directing my Secretaries of Health and Human Services and California Environmental Protection Agencies, working with our University and academic institutions, to develop a comprehensive approach to the laudable goals of this bill." The two agency secretaries subsequently directed staff from DHS, OEHHA and DTSC to collaborate on assembling the approach outlined in this document.

CECBP OVERVIEW

CECBP would routinely and systematically collect and archive blood and other human biological samples. DHS and DTSC laboratories would analyze the samples for specific

environmental contaminants. Program participants would be selected to comprise a statistically valid sample of California's population. CECBP would use CDC protocols for sample collection, field testing and data management. CECBP would also use CDC's contractor to train field staff and to develop a sampling strategy designed to obtain a representative sampling of California's population. That sample would include approximately 2,000 persons every two-year cycle of data collection and analysis. CECBP would analyze the results to determine baseline levels and time trends of the chemicals sampled. The sampling and analysis would be part of the core CECBP program. Some additional data would be obtained to assist researchers in evaluating the sample results (e.g., blood lipid levels needed to interpret fat-soluble chemical data).

One key objective of CECBP would be to coordinate with the CDC biomonitoring program to the greatest extent possible. This would reduce costs and allow for comparisons between the findings of the federal and California programs. CDC's approach is designed to obtain a representative sample of the United States population to draw conclusions for the country as a whole. However, these data do not represent California's population. To obtain a representative sampling of Californians, it will be necessary for CECBP's sample to include a broad range of ethnicities. Once California baseline levels are developed, it should be possible to compare the California baseline levels with CDC's national baseline levels for each of the chemicals included in California's program. This will indicate whether Californians have different levels of exposure to key toxic contaminants than the United States population as a whole, and whether patterns of varying exposure across ethnic, age and gender groups seen in California are similar to or differ from those seen in the national program.

With biomonitoring information gathered from a representative sample of California's population, OEHHA, DHS and DTSC could draw conclusions about state programs designed to reduce those exposures, and set priorities for future studies and regulatory actions. California could demonstrate national leadership through such a project by combining this direct monitoring technique with environmental protection activities.

The entire CECBP program would be guided by input from an external Scientific Guidance Panel (SGP) comprised of University researchers. At the same time, the biological samples collected by the program would represent a rich resource for researchers at California academic institutions. In partnership with CECBP staff, researchers could examine, for example, relationships between blood levels of environmental chemicals and specific chronic health conditions.

PROGRAM ARCHITECTURE/ SAMPLE COLLECTION AND ANALYSIS:
State staff would design CECBP, developing program protocols and guidelines consistent with CDC protocols. Contract staff, with input from the SGP, would carry out the field work, including identifying and recruiting participants, administering questionnaires, and scheduling clinic visits for sample collection. At the clinic site, appropriately trained staff would obtain basic physiological measurements and collect biological specimens, which would be labeled and shipped to DHS and DTSC laboratories, where samples would be stored on-site in secure freezers before analysis.

In the biological samples, CECBP laboratories would analyze persistent organic chemicals, metals, and non-persistent organic chemicals, and would provide descriptive statistical analysis of results from the samples. Prior to collection of samples in the field, high through-put laboratory methods would be developed and validated.

CECBP would conduct statistical and epidemiological analyses of biomonitoring results in relation to the participants' questionnaire data and physiological measurements.

DATABASE MANAGEMENT:
CECBP would be responsible for designing, developing, updating and maintaining the program database, which would store the collected data in a secure and confidential manner. The establishment of this database would be undertaken in part via a contract with the National Center for Health Statistics, which has extensive experience with similar large databases at the federal level. The CECBP would follow CDC's approach in collecting and releasing data. Each data-collection period would span two years, and reports on analyses of the data would be released initially at the end of the third year, and subsequently every two years. Information on time trends would evolve with each successive data-collection effort. Even after the first data-collection period, there would be worthwhile data to report, such as comparisons between chemical levels in Californians and the nation as a whole, or comparisons between different ethnicities and age groups in California.

PROGRAM COORDINATION:
CECBP would staff and support the CECBP Scientific Guidance Panel, draft and issue program reports, and conducting public education and outreach on program findings.

SCIENTIFIC GUIDANCE PANEL:
The CECBP Scientific Guidance Panel would provide scientific peer review of all aspects of implementation of CECBP. The Panel would be primarily comprised of experts from the University of California and other academic and scientific institutions. Members would include scientists with expertise in epidemiology, biostatistics, biochemistry, risk analysis, exposure assessment, environmental medicine, ethics and other disciplines. The Cal/EPA and HHSA secretaries would appoint panel members. The participation of academic experts on the panel is in keeping with the Governor's directive in the SB 600 veto statement for Cal/EPA and HHSA to work with experts in academia on approaches for a biomonitoring program.

REPORTING OF RESULTS:
OEHHA, DHS and DTSC would collaborate to draft and disseminate reports of CECBP findings. These collaborations would take place as part of each two-year period of data collection and analysis. In terms of individual results, only when either physiological or chemical data obtained from a given study subject indicates a significant known health risk, would the CECBP notify that individual and recommend consultation with a physician. Participants would not receive results of their own blood levels of chemicals for which there are no recognized clinical action criteria. The CDC program follows the same practice.

One concern that is frequently raised about biomonitoring programs is that the findings could cause undue public alarm, particularly if there is significant media coverage. Experience indicates that this does not occur. The CDC program, which involves the biomonitoring of numerous substances whose health effects are not certain, has not resulted in controversy or public alarm. CDC has emphasized that the detection of a chemical in the body does not automatically mean there is a health risk. California's program could employ similar protocols and language to prevent unnecessary controversy.

EDUCATION AND OUTREACH:
CECBP would develop fact sheets and other written materials that explain the activities and findings of the CECBP related to environmental chemicals. CECBP would also develop a Web page with CECBP reports, fact sheets and other relevant materials. CECBP would participate in public meetings and other public forums for the purpose of educating and informing the public about the program in general, as well as specific study findings.

CECBP would provide opportunities for public input during development and operation of the program. CECBP would conduct four public workshops in Northern and Southern California and the Central Valley during the development of the CECBP to receive community input and recommendations on CECBP provisions and operation. In addition, the Scientific Guidance Panel would hold periodic public meetings under the provisions of the Bagley-Keene Open Meetings Act (Government Code 11120, et seq). The public would be welcome to attend these meetings, and there would be ample opportunities for public comment at the meetings.

Chemical Selection Process

The selection of chemicals for the program would consist of substances that are included in the CDC program. Each of these chemical families (or, if metabolites are biomonitored, their parent chemicals) would need to have established exposure limits, or be subject to environmental regulations. The SGP will need to prioritize chemicals for inclusion in the program and will use the following as prioritization criteria:

- The chemical has an established, peer-reviewed health standard
- Degree of potential exposure to the public or specific subgroups (e.g., occupational)
- Likelihood of a chemical being a carcinogen or toxicant based on risk assessment, the chemical structure or based on toxicology of chemically related compounds
- Limits of detection – the ability to detect the chemical at low enough levels that could be expected in the general population
- Other criteria that the group may agree to

Program development and implementation timeline

Program activities during the first two years would include:

- Recruitment and hiring of program staff
- Development of a multi-year plan
- Identifying and appointing members of the Scientific Guidance Panel and holding initial Panel meetings
- Study design and sampling activities, such as preparing contracts, developing and refining a study protocol, and questionnaire development and testing
- Data management system design, development and testing
- Purchase and installation of laboratory equipment, and development and/or validation of analytical methods
- Public education and outreach, including development of background materials, consultation with interested organizations and professional groups, and development of the program website
- A “dress-rehearsal” of sampling and analysis, including pilot-testing methods for participant recruitment, sample collection and analysis, data management, and quality assurance/quality control

In the third year of the program, implementation of the full program would begin.

Next Steps

With each two-year data-collection cycle, CECBP scientists and others could use data to evaluate trends in chemical levels over time, and to determine if regulatory programs pertaining to biomonitored chemicals are having their desired impact. Once baseline levels are established, the program would have the option of conducting additional biomonitoring studies focusing on specific communities or groups that may have higher exposures to chemicals of concern relative to the general population. In addition, CECBP or other programs or researchers could use data from the CECBP and CDC programs to investigate the reasons why exposures in California to specific chemicals may be different than in the nation as a whole. In many cases, these follow-up evaluations would not have to be conducted by CECBP, but instead could be conducted by other state programs or outside researchers using CECBP data. Any additions or changes to the CECBP program would be made only with the advice and counsel of the scientific guidance panel.